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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/120, 044      07/21/98      MINETTI

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EXAMINER

ART UNIT	PAPER NUMBER
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1645

*18*

DATE MAILED:

07/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/120,044

Applicant(s)

Minetti et al.

Examiner

S. Devi, Ph.D.

Group Art Unit

1645

 Responsive to communication(s) filed on 05/12/2000. This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

 Claim(s) 1-34  are pending in the application.

Of the above, claim(s) 8-11, 16-21, and 27-30  are withdrawn from consideration.

 Claim(s) 12-15  are allowed. Claim(s) 1-7, 22-26 and 31-34  are rejected. Claim(s) \_\_\_\_\_  is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

 See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

 Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### **Change of Art Unit Location**

- 1) Effective 20 June 2000, the Art Unit location of your application in the US PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1645.

### **Applicants' Amendment**

- 2) Acknowledgment is made of Applicants' amendment filed 05/12/2000 (paper no. 16) in response to the Office Action mailed 11/09/99 (paper no. 13). With this amendment, Applicants have amended certain parts of the specification.

### **Status of Claims**

- 3) Claims 1, 2, 4-6, 13, 22-24 and 26 have been amended via the amendment filed 5/12/2000. New claims 31-34 have been added via the amendment filed 5/12/2000. Claims 1-34 are pending. Claims 1-7, 12-15, 22-26 and 31-34 are under examination.

### **Prior Citation of Title 35 Sections**

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Drawings**

- 6) The informal drawings filed in this application were accepted for examination purposes only. Formal drawings will be required when the application is allowed.

### **Objection(s) Withdrawn**

- 7) The objections to claims 3-6, 13, 23 and 26 made in paragraph 16 of the Office Action mailed 11/09/99 (paper no. 13) are withdrawn in light of Applicants' amendments to the claims.

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8) The objection to the specification made in paragraph 8 of the Office Action mailed 11/09/99 (paper no. 13) with regard to the designation "PLYD" mutants "A" and "B", is withdrawn.

**Rejection(s) Withdrawn**

9) The rejection of claims 1-3 and 22-26 made in paragraph 9 of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' amendments to the claims.

10) The rejection of claims 4-7 made in paragraph 10 of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, first paragraph, as being non-enabled is withdrawn in light of Applicants' amendments to the claims.

11) The rejection of claim 2 made in paragraph 12(a) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite for lacking a SEQ ID NO. is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claim 1 made in paragraph 12(b) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claim 1 made in paragraph 12(c) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, with regard to the recitation "substantially", is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 2 made in paragraph 12(d) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, with regard to the recitation "properly-refoldable", is withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claims 22 and 25 made in paragraph 12(e) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

16) The rejection of claims 23 and 26 made in paragraph 12(f) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

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- 17) The rejection of claim 24 made in paragraph 12(g) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 18) The rejection of claim 24 made in paragraph 12(h) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 19) The rejection of claim 26 made in paragraph 12(I) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 20) The rejection of claim 26 made in paragraph 12(j) of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 21) The rejection of claim 1 made in paragraph 14 of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 102(b) as being anticipated by Lock *et al.* (*Microb. Pathogen.* 21: 71-83, 1996) is withdrawn in light of Applicants' amendment to the claim.
- 22) The rejection of claims 1 and 22-26 made in paragraph 15 of the Office Action mailed 11/09/99 (paper no. 13) under 35 U.S.C § 102(b) as being anticipated by Paton *et al.* (*Infect. Immun.* 59: 2297-2304, 1991) is withdrawn in light of Applicants' amendment to the claims or the base claim.

#### **New Rejection(s)**

- 23) Applicants are asked to note the new rejection made in this Office Action. The Applicants' amendments including addition of new claims necessitated the new grounds of rejection(s) presented in this Office Action.

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph**

- 24) Claims 1-7, 22-26 and 31-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1 and 2, as amended, currently encompass a modified refoldable pneumolysin having attenuated hemolytic activity comprising an amino acid sequence of type 14 pneumolysin wherein at least one amino acid in the region comprising amino acid residues 1 to 257 of SEQ ID NO: 3 is substituted, "besides a substitution of threonine for isoleucine at amino acid 172". However, there appears to be no support in the instant specification for this added limitation. Further, Applicants have **not** pointed to the specific parts of the disclosure that support this newly added limitation or amendment to the claims. Therefore, the above-identified new limitation in the claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the newly added limitation, or to remove the new matter from the claims.

25) Claims 1-7, 22-26 and 31-34 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-7 and 22-26 as amended and new claims 31-34 that depends from amended claims encompass a modified refoldable pneumolysin polypeptide having attenuated hemolytic activity comprising an amino acid sequence of type 14 pneumolysin wherein at least one amino acid in the region comprising amino acid residues 1 to 257 of SEQ ID NO: 3 is substituted, "besides a substitution of threonine for isoleucine at amino acid 172". The basis requirement of the claimed modified, attenuated, refoldable type 14 pneumolysin is that it should have a substitution "of threonine for isoleucine at position 172" of the pneumolysin sequence and at least one amino acid substitution in the region comprising amino acid residues 1 to 257 of SEQ ID NO: 3. However, there is no isoleucine at position 172 of the wild type, type 14 pneumolysin to substitute with threonine. See Table 5A for example. There appears to be no evidence within the instant specification enabling a modified pneumolysin comprising a substitution "of threonine for isoleucine at amino acid 172", with or without having refoldable and attenuated hemolytic

properties. The wild type, type 14 pneumolysin, as shown in Table 5A for example, has a threonine at position 172, not isoleucine. One cannot substitute "threonine for isoleucine at position 172" of the wild type, type 14 pneumolysin when there is no isoleucine at position 172 in the type 14 wild type pneumolysin sequence, as disclosed. The only mutant described in the instant specification, pNJ45, which has an amino acid substitution at position 172 carries an alanine substituted for threonine at position 172, not "threonine for isoleucine" substitution, as recited in the base claims. The basic requirement itself for the product claimed is non-enabled. What is claimed is not enabled. The recited functions of refoldability and attenuated hemolytic activity of the claimed product cannot be attributed to a modification or substitution that has not been made by the Applicants and that cannot be made by one of ordinary skill in the art even with undue experimentation.

#### Remarks

26) Claims 12-15 stand allowed. Claims 1-7, 22-26 and 31-34 stand rejected.

27) **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242.

29) Any inquiry concerning this communication or earlier communication(s) from the

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Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 8.00 a.m to 4.00 p.m. A message may be left on the Examiner's voice mail service.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD  
S. Devi  
Patent Examiner  
July 2000

*Lynette R. F. Smith*  
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